

1 HONORABLE ROBERT S. LASNIK
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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

9 EXPEDIA, INC., and HOTELS.COM, L.P.,
10 Plaintiffs,
11 v.
12 PRICELINE.COM INCORPORATED,
13 Defendant.
14

Case No.: 2:09-cv-00712-RSL

**DECLARATION OF CHRISTINE H.
MILLER IN SUPPORT OF
DEFENDANT'S MOTION TO STAY
AND DISMISS**

DECLARATION OF CHRISTINE H. MILLER

CHRISTINE H. MILLER, under penalty of perjury, declares as follows:

1. I am Counsel at the law firm Patterson Belknap Webb & Tyler LLP which
represents Defendant Priceline.com Incorporated ("Priceline") in this action. I represented
Priceline in all aspects of the December 2008 challenge that Expedia, Inc. and Hotels.com
("Expedia") brought against Priceline before the National Advertising Division of the Council
of Better Business Bureaus ("NAD"). I submit this declaration, based upon my personal
knowledge, in support of Priceline's motion to stay and dismiss.

2. I am an attorney admitted to the bar of the State of New York. For more than 20
years, my practice has been devoted primarily to representing clients in advertising and

25 DECLARATION OF CHRISTINE H. MILLER ISO
DEFENDANT'S MOTION TO STAY AND DISMISS - 1
Case No. 2:90-cv-00712-RSL

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1 trademark matters. I appear regularly before NAD on behalf of clients disputing competitors' advertising and clients whose advertising has been questioned. Since 1989, I have handled over
 2 fifty NAD challenges, compliance proceedings and appeals on behalf of various clients. I also
 3 have served on the planning committee for NAD's annual conference on advertising law. By
 4 virtue of these experiences, I am very familiar with the policies and procedures that govern the
 5 NAD forum.

6 3. In its brief in opposition to Priceline's motion to stay and dismiss, Expedia states
 7 that at the time Expedia commenced this litigation "neither Expedia nor Priceline knew what
 8 NAD's decision [in Expedia's December 2008 challenge] would be." (Pl. Br. Opp. At 6) I
 9 disagree.

10 4. On May 4, 2009, Priceline met with NAD to discuss Expedia's challenge.
 11 Priceline's NAD meeting was typical of other NAD meetings I have attended inasmuch as the
 12 responsible NAD staff attorney and NAD's director, Andrea Levine, engaged in a frank
 13 discussion of Expedia's challenge and shared their perspectives on the parties' positions.

14 5. During Priceline's meeting, Ms. Levine made several comments regarding the
 15 merits of Expedia's challenge. Among them, Ms. Levine indicated that she was satisfied that
 16 Priceline's "up to 50%" savings claims are adequately substantiated by Priceline's methodology
 17 for comparing the hotel rates paid by actual Name Your Own Price customers against the rates
 18 those customers would have paid if they had booked their same itineraries through competitors'
 19 published price sites. She also stated that she did not have a problem with Priceline's "Tough
 20 Love" television commercial because it makes clear that the "up to 50%" savings claim pertains
 21 to hotels booked through Name Your Own Price. I therefore left the meeting fully expecting
 22 that NAD would rule in Priceline's favor. Based on my experience, it would be unusual for
 23 NAD to share these views with one party but not the other.

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 25 DECLARATION OF CHRISTINE H. MILLER ISO
 DEFENDANT'S MOTION TO STAY AND DISMISS - 2
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6. Expedia also states in its opposition brief that “NAD would have to violate its own operating rules” to reopen Expedia’s December 2008 challenge now that litigation has commenced. (Pl. Opp. Br. at 15) In my experience, however, when NAD administratively closes an investigation because the ads under review have become the subject of litigation, NAD often issues a public statement reserving the right to re-open its investigation in the event that the court does not reach a decision on the merits. NAD issued such a statement in a prior challenge in which I represented the advertiser. *See Discus Dental, Inc.* (BreathRx Oral Care Products), NAD Case Report # 4473 (4/14/06), p. 13 (A copy of NAD’s decision in that challenge is attached as Exhibit A).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information and belief.

Executed at New York, New York this 10th day of September, 2009.

By: Christine H. Miller
Christine H. Miller

**DECLARATION OF CHRISTINE H. MILLER ISO
DEFENDANT'S MOTION TO STAY AND DISMISS - 3**
Case No. 2:90-cv-00712-RSL

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EXHIBIT A

Case #4473 (04/14/06)

DISCUS DENTAL, INC.

BreathRx Fresh Breath System (Oral Care Products)

Advertising Agency: Undisclosed
Challenger: Pfizer, Inc.

- It is well established that an advertiser is obligated to support all reasonable interpretations of claims made in advertising including messages it may not have intended to convey.

Basis of Inquiry: Claims made by Discus Dental, Inc. for its BreathRx Fresh Breath System (Oral Care Products) in print, packaging, television and Internet advertising were challenged by Pfizer, Inc., manufacturer of Listerine Antiseptic Mouthwash. The challenger took issue with, among other things, the advertiser's purported failure to disclose that its expert endorser in BreathRx television commercials and other marketing materials is, in fact, the founder and owner of Discus Dental, Inc. The challenger also took issue with the advertiser's use of the "Rx" symbol on products and in advertising. The challenger also questioned the advertiser's use of the claim "America's #1 Dentist Dispensed Breath Care System" on individual components of the BreathRx System and, lastly, asserted that print advertisements conveyed a misleading characterization of the alcohol content in the challenger's Listerine product.

The Challenger's Position:¹

I. Failure to Disclose Material Connection of Expert Endorser to Discus Dental, Inc.:

The challenger noted that in the opening scene of the BreathRx television commercial, Dr. Bill Dorfman appears with a written super showing his name and identifying him as "America's Dentist." Dr. Dorfman then introduces himself: "Hi, I'm Dr. Bill Dorfman, the dentist from Extreme Makeover. I know a lot of people worry about taking care of bad breath" whereupon the commercial cuts away to a woman who is frustrated about the ineffectiveness of other bad breath treatments, and then returns to Dr. Dorfman's voiceover, which continues: "That's why I recommend BreathRx, not only to my patients, but to everybody I know."

The challenger pointed out that the FTC has made clear that when "there exists a connection between the endorser and the seller of the advertised product which might materially affect the weight or credibility of the endorsement (i.e., the connection is not reasonably expected by the audience) such connection must be fully disclosed."² In this case, the challenger stated, the crux of the commercial is Dr. Dorfman's endorsement, but the commercial does not disclose that he is the founder and owner of Discus Dental,³ the manufacturer of the advertised product.

¹ The challenger also took issue with the truth and accuracy of the advertiser's claims, "America's #1 Dentist Dispensed Breath Care System" and "Clinically proven more effective at fighting bad breath than leading brands, including Listerine." For reasons to be discussed, *infra* NAD administratively closed its inquiry with respect to these claims.

² FTC Guidelines Concerning Use of Endorsements and Testimonials in Advertising, 45 Fed. Reg. 3873, January 18, 1980.

³ Citing Discus Dental, Inc. (Zoom! Chairside Tooth Whitening System), Report #4009, *NAD Case Reports*, (January 2003) (noting Dr. Dorfman as "the owner of Discus Dental").

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 2

It was the challenger's position that, as founder and owner of Discus Dental, Dr. Dorfman has economic and managerial control of the day-to-day affairs of the company, and therefore also has a substantial interest in the financial success of BreathRx products – a connection that cannot reasonably be expected to be ascertained by the average viewer of the commercial, and would undoubtedly influence how a prospective purchaser judges the credibility of Dr. Dorfman's endorsement. Indeed, the challenger argued, the fact that Dr. Dorfman identifies himself as a "doctor" and "the dentist from Extreme Makeover" adds to the likelihood that consumers would place great weight in his recommendations, further militating in favor of full and fair disclosure of his material connections to Discus Dental.

The challenger added that the advertiser cannot overcome the "material connections" disclosure requirement by invoking the FTC's disclosure exemptions for experts and celebrity endorsers because that exemption does not assume that the endorser has other material connections to the company, such as being a stakeholder. According to the challenger, in any and all advertising in which Dr. Dorfman endorses BreathRx products, the advertiser must add prominent disclosures about his connections to the company.

II. Misuse of "Rx" Symbol in Products and Advertising.

The challenger contended that the advertiser's use of the "Rx" symbol and other statements in the very name of its line of oral care products constitutes inappropriate marketing of non-prescription products and misleads consumers into believing that they are purchasing prescription products. According to the challenger, both the FDA and the NAD have recognized that the use of the "Rx" symbol to market non-prescription products may be inappropriate. For example, the FDA requested that the marketers of "Arizona Rx Stress Relief Elixir" remove "the prescription symbols and the other phrases and terms that suggest this product is a Rx drug . . ." because of the unavoidable suggestion that the product is a prescription product.⁴ Further, the challenger pointed out, NAD has also noted the potential that "use of the term 'Rx' may deceive consumers into thinking that they are purchasing drugs without a prescription."⁵

While acknowledging that the use of the "Rx" symbol in a product name alone does not ipso facto mean that consumers are being misled that they are purchasing prescription products, the challenger posited that the "BreathRx" name appears to be deliberately marketed so as to create this misimpression. For example, the challenger pointed out, many BreathRx products feature the claim "Professional Formula" in capitalized letters above the "BreathRx" logo, conveying the impression that the consumer is purchasing a prescription-strength product. Further, the challenger noted, many individual BreathRx products prominently display the claim "America's #1 Dentist-Dispensed Breath Care System!" It was the challenger's position that by invoking the term "Dentist-Dispensed" in such close proximity to the "Rx" symbol, the advertiser further creates a nexus between BreathRx products and medications dispensed by licensed physicians.

⁴ See FDA Warning Letter ONPLDS 02-00, May 15, 2000.

⁵ See, Hornell Brewing Company (Arizona Rx Memory Mind Elixir), Report #3736, *NAD Case Reports* (March 2001)

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 3

These claims, the challenger contended, piggyback on consumer impressions that BreathRx products have traditionally been available through dental offices, and create an environment where consumers are misled into thinking that they can now purchase prescription oral care products without a prescription or the intervention of a dental professional.⁶

III. Misuse of the Claim “America’s #1 Dentist Dispensed Breath Care System” on Individual BreathRx Products.

With respect to the claim that Breath Rx is “America’s #1 Dentist-Dispensed Breath Care System” on individual products, the challenger asserted that, assuming *arguendo* that the “System” is “America’s #1 Dentist Dispensed Breath Care System,” it is unclear whether this claim is true for *all* BreathRx products bearing that claim. Thus, even if substantiated and literally true, the challenger asserted that the advertiser’s use of this claims is overly broad. According to BreathRx’s website, it appears that the BreathRx “Breath Care System” is sold as a unit and is comprised of three products: (1) the BreathRx Purifying Toothpaste; (2) the BreathRx Gentle Tongue Scraper and BreathRx Anti-Bacterial Tongue Spray; and (3) the BreathRx Anti-Bacterial Mouth Rinse. This, the challenger asserted, is also confirmed by the advertiser’s commercials describing a three-step process.

The challenger pointed out that, although the claim refers to a specific set of products sold and intended to be used together, the claim “America’s #1 Dentist-Dispensed Breath Care System” appears on other unrelated products, such as BreathRx Dental Floss and BreathRx Anti-Bacterial Breath Spray. According to the challenger, there is no basis for the claim appearing on these unrelated products. Further, the claim also appears on each component item of the “System” when those items are sold individually. The challenger argued that unless *each* of BreathRx’s components (Toothpaste, Tongue Scraper, Tongue Spray, and Mouth Rinse) can individually be touted as “America’s #1 Dentist-Dispensed Breath Care System,” this claim is false and misleading as used. Moreover, the challenger maintained, the claim, as used on the BreathRx Mouth Rinse on a stand-alone basis can only be interpreted as a superiority claim for BreathRx Mouth Rinse versus all other mouthwash products, including Listerine, the leading over-the-counter mouthwash which has consistently been the mouthwash most recommended by dentists and hygienists, which cannot be substantiated.

Thus, the challenger asserted, the advertiser’s use of this claim on unrelated and stand-alone products is anathema to advertising best practices that require an advertiser to clearly indicate the exact product to which an endorsement refers. Indeed, the challenger contended, where that endorsement is a superiority claim, such as here, that requirement becomes even more important. The challenger maintained that, assuming that the advertiser has adequate substantiation of its “Dentist-Dispensed” claim, this claim should only appear on the specific product to which it refers, that being the “Breath Care System,” and only when sold as a unit.

⁶ If BreathRx is in fact “America’s #1 Dentist-Dispensed Breath Care System,” the challenger asserted that that per se suggests a strong association between BreathRx products and dentist-prescribed remedies. That association is not lost on Discus Dental, which stokes the fire by claiming in its television commercials that “BreathRx was only available in dentists’ offices until now. Visit walgreens.com or cvs.com to order today.” See Exhibit A.)

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 4

IV. Misleading Characterization of the Alcohol Content in Listerine.

The challenger asserted that certain print advertisements mischaracterized the alcohol content in its Listerine products. These advertisements, appearing in professional journals read: “Do you really know who you’re giving alcohol to?”⁷ In response to this question, the advertisements answer “children,” “recovering alcoholics,” “xerostomia patients,” “smokers,” “patients with restorations,” radiation therapy patients,” “elderly patients,” “pregnant and lactating women,” “diabetics,” and “patients on medication.” The advertisement also highlights a portion of a Listerine label that details its alcohol content and states “A leading brand . . . THAT’S 43 PROOF!” According to the challenger, this misrepresents the nature and effects of the alcohol that is contained in Listerine, which is present as a pharmaceutical necessity to solubilize the active ingredients.

First, the challenger asserted, although containing a percentage of alcohol, Listerine has *never* been promoted for children. In fact, warnings appear on the label of Listerine bottles cautioning users “Do not administer to children under six years of age” and that they should “[k]eep out of reach of children.” Indeed, the challenger noted, the product labeling for the advertiser’s *BreathRx* contains the warning “Do not administer to children under age six . . . Supervise use for children between ages six and twelve.” The challenger argued that, in the context of a comparative advertisement urging dental professionals to use an “alcohol-free alternative,” Discus Dental’s reference to “children” as a user group of Listerine conveys the false impression that *BreathRx* is safe for use by all children.

Second, the challenger argued, notwithstanding that Listerine has never been promoted for ingestion, the advertisement equates using Listerine with “giving alcohol” to people, including “recovering alcoholics,” and equates the 21.6% alcohol-level in Listerine to being “43 proof,” as if Listerine were an alcoholic beverage with intoxicating effects. Both comparisons are false and highly misleading. Listerine is an expectorated product and is not intended for ingestion. Listerine contains specially denatured alcohol (“SDA”), i.e. alcohol to which denaturants have been added in order to make it unfit for consumption or internal human medicinal use, according to specific Bureau of Alcohol, Tobacco and Firearms regulations authorizing the use of alcohol in mouthwashes. The challenger asserted that it is highly damaging to Listerine’s reputation, as well as to its safety and efficacy profile that has been established for over 125 years to imply under any circumstances that the specially denatured alcohol contained in Listerine is commensurate with an alcoholic beverage.⁸ The safety and efficacy of Listerine was evaluated by the Dental Plaque Subcommittee of the Nonprescription Drugs Advisory Committee as part of the FDA’s ongoing review of drug products. It was the Subcommittee’s conclusion that Listerine (fixed combination of essential oils in a mouthrinse containing 21.6% to 26.9%

⁷ Citing two executions in at least the following journals: The Journal of Practical Hygiene (June 2005), Dimensions of Dental Hygiene (May, June and August 2005), Woman Dentist Journal (May and June 2005), Contemporary Oral Hygiene (May, June and August 2005), and Access (July 2005).

⁸ Denatured alcohol is regulated by the Bureau of Alcohol, Tobacco and Firearms under 427 C.F.R. Parts 20-21.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 5

alcohol) is safe and effective and Listerine was recommended for inclusion in the antigingivitis/antiplaque over-the-counter drug products monograph.⁹ Listerine has also been found to be safe and effective for its labeled indications by the American Dental Association (“ADA”), and Listerine carries the ADA Seal of Acceptance which, interestingly, the advertiser’s BreathRx does not.

Lastly, the challenger stated, Listerine is *not* contra-indicated for xerostomia patients, smokers, patients with restorations, radiation therapy patients, elderly patients, pregnant and lactating women, diabetics, or patients on medication. While select individuals in the foregoing groups may receive advice from their physicians to favor a particular type of mouthwash (for reasons related or unrelated to their condition), such advice would be highly individualized and broad statements implying that alcohol-based mouthwashes are generally inappropriate for entire patient groups are gross and unsupportable generalizations.

The Advertiser’s Position:

The advertiser explained that the BreathRx Fresh Breath System provides consumers with a highly effective, alcohol-free remedy for chronic oral malodor, commonly known as persistent bad breath. Developed in 1997, the BreathRx Breath Care System was dentist-dispensed and marketed exclusively to dental professionals until February 2004. In 2004, BreathRx first became available to consumers through the BreathRx website and third-party website retailers (e.g., drugstore.com and Amazon.com), and later through additional traditional retail channels. The first national BreathRx television commercial aired in May 2005.

The advertiser further explained that the BreathRx System is a 3-step treatment consisting of: (1) brushing with the BreathRx toothpaste; (2) scraping the tongue with BreathRx tongue spray and tongue scraper; and (3) rinsing with BreathRx mouth rinse. In addition to containing fluoride, the toothpaste contains Zytex¹⁰ to combat oral malodor. The second step involves the use of an anti-bacterial tongue spray and scraper to remove the bacteria trapped in the tissue of the back of the tongue that emit volatile sulphur compounds, or VSCs, the foul-smelling odor associated with bad breath. The third step is the BreathRx Mouth Rinse, which is alcohol-free and contains Zytex and cetylpyridinium chloride.

I. Dr. Dorfman’s Connection to Discus Dental is Disclosed

The advertiser asserted that spokesperson Dr. Dorfman is not only a dentist, but a celebrity as well. Dr. Dorfman identifies himself in the commercials as “Dr. Bill, the dentist from Extreme Makeover” – a show, the advertiser noted, that has had as many as 11.3 million viewers in one night during 2004 such that, any consumer would expect a celebrity like Dr. Dorfman to receive compensation for his endorsement . The challenger noted that the FTC makes clear that the amount and form of that compensation is immaterial so long as consumers recognize that the

⁹ 68 F.R. 32232, ANPR: Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis / Antiplaque Products (May 29, 2003).

¹⁰ a proprietary blend of eucalyptus oil, thymol, and zinc gluconate

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 6

endorser is being compensated¹¹ and asserted that Dr. Dorfman's endorsement of BreathRx fulfills the requirements of the FTC's Guidelines because he is a well-known personality and the advertiser does not represent that he appeared without compensation. The advertiser added that the fact that some of Dr. Dorfman's payment for his endorsement may come from the sales of BreathRx as co-owner of Discus Dental is immaterial as the Guidelines state that "even though the compensation paid the endorser is substantial, neither the fact nor the amount of compensation need be revealed."¹² Thus, the advertiser contended that it is under no obligation to make the kind of disclosure suggested by the challenger.

In any event, the advertiser stated that in its television commercials, it *does* disclose in dark text against a light background in legible type appearing directly next to Dr. Dorfman's image at the start of the commercials stating: "Co-Founder Discus Dental."

II. The BreathRx Product Name is not Misleading

The advertiser asserted that the use of the letters "Rx" in the product name of the toothpaste, tongue scraper, and mouthwash that are sold over the counter alongside other non-prescription oral hygiene products does not convey the message that these are prescription products. The advertiser asserted that the BreathRx label does not contain the Rx symbol, the letters Rx do not stand alone but are fully incorporated into the product name BreathRx and the challenger cannot point to any other language currently being used on the BreathRx labels that would cause that type of confusion. In any event, the advertiser asserted, the challenger offered no evidence to support its contention that the BreathRx name is misleading to consumers, despite the fact that NAD has repeatedly held that an advertiser will not be required to change the name of a product in the absence of extrinsic evidence that consumers have been confused or misled.¹³

The advertiser added that common sense dictates that the inclusion of the letters "Rx" in the name BreathRx does not mislead consumers into believing that over-the-counter mouthwash, toothpaste, and tongue scraper are prescription products. A commonly understood definition of the letters "Rx" is "a remedy, cure, or solution for a disorder or problem"¹⁴ – which is precisely what BreathRx delivers – a remedy for the problem of oral malodor.

¹¹ Citing § 255.5 of the FTC Guides Concerning Use of Endorsements and Testimonials in Advertising, www.ftc.gov/bcp/guides/endorse.htm; 45 Fed. Reg. 3873, January 18, 1980

¹² Id.

¹³ See Coca-Cola Company (Powerade Option Low Calorie Sports Drink), Report # 4438, *NAD Case Reports* (January 12, 2006); Bissell Homecare, Inc. (Bissell QuickSteamer® Plus, Bissell PowerSteamer® Plus ProHeat® Deep Cleaning Machines), Report # 4145, *NAD Case Reports* (February 13, 2004); CCA Industries, Inc. (Scar Zone Topical Scar Diminishing Cream with SPF15 and Silicone), Report # 4018, *NAD Case Reports* (March 2003); IGIA (Never Snore), Report # 3968, *NAD Case Reports* (November 2002).

¹⁴ Citing The American Heritage Dictionary of the English Language, Fourth Edition (2000)

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 7

The advertiser further pointed to other instances where the letters “Rx” have been used in a variety of non-prescription products.¹⁵ Further, the advertiser pointed out, after modifying the claims on its product labels following a determination by NAD,¹⁶ Arizona Beverage Company continues to use the Rx symbol in its Rx Memory, Rx Stress, Rx Health, and Rx Energy herbal iced teas. It was the advertiser’s position that consumers’ regular exposure to non-prescription products employing the symbol “Rx” makes it highly unlikely that the BreathRx products would be mistaken for prescription drugs.

With respect to the challenger’s notation of two statements on the product label to bolster its claim that the Rx portion of the name is misleading: (1) the words “Professional Formula” on certain Mouth Rinse labels; and (2) “The #1 Dentist Dispensed Breath Care System” the advertiser countered that neither statement supports the challenger’s position. First, the “Professional Formula” language on some BreathRx products first appeared on certain packaging when the product was sold only to dental professionals and has since been discontinued. The advertiser noted that it was already in the process of changing this aspect of its label before the commencement of the instant challenge and, as such, under Rule 2.2B(i)(d), the prior label should not be considered by NAD.

With respect to the challenger’s contention that “by invoking the term ‘dentist-dispensed’ in the same eyeshot as the ‘Rx’ symbol, Discus dental further creates a nexus between BreathRx products and medications dispensed by licensed physicians” the advertiser asserted that this argument runs contrary to the day-to-day experiences of consumers who regularly obtain non-prescription products such as toothbrushes, dental floss, and mouthwash from their dentists and dental hygienists, and contradicts NAD precedent.¹⁷

III. The Advertiser’s Use of the System-Specific Claim on Packaging of System Components is Truthful and Accurate:

The advertiser asserted that, contrary to the challenger’s position, its use of the #1 Dentist-Dispensed System Claim on its toothpaste, dental floss, tongue spray, tongue scraper, and mouth

¹⁵ i.e., Frederic Fekkai has a line of hair products using the letters “Rx,” including Protein Rx Reparative Treatment Mask; Met-Rx offers a variety of protein bars and drink mixes, including the Met-Rx Big 100 Meal Replacement Bar and Met-Rx Meal Replacement Powder; and Arth-Rx topical analgesic is sold over the counter to relieve the pain associated with arthritis.

¹⁶ Hornell Brewing Company (Arizona Rx Memory Mind Elixer), Report # 3736, *NAD Case Reports* (March 8, 2001).

¹⁷ Merial Limited (FRONTLINE Plus Flea and Tick Treatment), Report # 3844, *NAD Case Reports* (12/18/2001). In this case, the advertiser contended, the challenger argued in part, that the presence of a veterinarian in a television commercial recommending the flea and tick treatment product “creates the false impression that [the product] is a prescription product.” NAD concluded that consumers are accustomed to doctors recommending non-prescription products and recognized that numerous non-prescription products are dispensed by veterinarians – just as numerous non-prescription products are dispensed by dentists. NAD further found that because the product at issue was dispensed solely through veterinarians, the use of a veterinarian in the commercial provided useful information to consumers about where they can purchase the advertised product. Here, BreathRx products are available through some dental offices, making the dentist-dispensed reference accurate and useful to consumers.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 8

rinse is appropriate because each of these products is a component of the BreathRx Fresh Breath System.¹⁸ Moreover, the #1 Dispensed System Claim always plainly relates to the entire system and not to the individual products.

The advertiser explained that the BreathRx Fresh Breath System consists of three main steps, “Brush,” “Scrape,” and “Rinse.” The product labels bear a logo that shows the three main steps in the system together, with that product’s applicable step highlighted in white. In addition, each main step has its own icon utilizing a descriptive graphic and text, which is clearly displayed on the center of the front of each product. Two of the main steps in the system have more than one component – a fact that is clearly described on the products’ packaging. The “Brush” step, the advertiser asserted, includes flossing, as demonstrated by the “Brush and Floss” icon displayed on the new floss packaging, and the description of the “Brush and Floss” step in recent advertisements and on the packaging of the BreathRx Introductory Kit.¹⁹ Further, the BreathRx Purifying Toothpaste and the BreathRx Dental Floss are available on the BreathRx website only under the heading “Brush.” Likewise, the “Scrape” step involves two steps: the use of the BreathRx Anti-Bacterial Tongue Spray before using the Tongue Scraper.

The advertiser contended that it is appropriate and not misleading to employ the #1 Dispensed System Claim on each product within the BreathRx Fresh Breath System, which consists of Purifying Toothpaste, Dental Floss, Anti-Bacterial Tongue Spray, Tongue Scraper, and Anti-Bacterial Mouth Rinse. The advertiser noted that on all of the packaging of BreathRx Fresh Breath System products, whether sold individually or together, the multi-step system is clearly identified both by text and icons. For example, on the mouth rinse bottle, the “rinse” icon appears in the center of the front of the label. On the back of the bottle, the three-step system icon appears at the top center of the label with the “rinse” step highlighted. On the front of the Introductory Kit packaging, the three brush, scrape and rinse icons appear and the back of the package has all three icons with the words “step 1” “step 2” and “step 3” above each in clear text. The text of the back of the package describes the first step as “brush and floss.” Directly underneath that language is the word “scrape” with text explaining the usefulness of using the tongue spray and scraper, along with instructions for using these products. Finally, the last step “rinse” appears with text explaining the benefit of using the mouth rinse. The individual and system icons appear on each component of the system to help consumers identify replacement components of the system. Because the products are clearly identified as components of a system, the advertiser asserted that it is entitled to display the #1 Dispensed System Claim on each of these products.

¹⁸ With respect to the BreathRx Anti-Bacterial Breath Spray, the advertiser stated that this product is available for refreshing ones breath between uses of the BreathRx Fresh Breath System and, although related to the BreathRx Fresh Breath System components and used by consumers when use of the BreathRx Fresh Breath System is impractical, the advertiser has voluntarily decided to stop using the #1 Dispensed System Claim on the Anti-Bacterial Breath Spray packaging.

¹⁹ The advertiser pointed out that the back of the Introductory Kit describes the “Brush” step as follows: “Brush and Floss: The Purifying Toothpaste’s breakthrough formula goes beyond fluoride protection to attack bacteria and neutralize bad odors. BreathRx Dental Floss deposits Zytex between the teeth where brushing can’t reach.”

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 9

In addition, the advertiser argued, its use of the #1 Dispensed System Claim on the individual components of the system is appropriate because the claim unmistakably relates to the entire system, not to the individual products. The advertiser noted that it never uses the words “America’s #1” without the accompanying “Dentist-Dispensed Breath Care System.”

IV. The Advertiser’s Position that its Claims as to Comparative Alcohol Content are Truthful, Accurate and Provides Useful Information to Dentists

The advertiser asserted that the purpose of the advertisement, which appears only in professional publications targeted at dental professionals, is twofold: (1) to inform dental professionals about the high alcohol content in Listerine, of which they may not be aware, and (2) to identify populations who are advised to avoid putting alcohol into their mouths (whether or not they intentionally ingest that alcohol) and in which alcohol-based mouthwashes may cause negative effects. These claims, the advertiser asserted, are accurate and substantiated.

The advertiser further asserted that the target audience of this advertisement, appearing only in professional journals, is dental professionals, a group of highly educated individuals who understand that mouthwash, of any variety, is not intended for consumption. Nevertheless, they are entitled to consider whether the risk of transdermal absorption and inadvertent or deliberate ingestion warrants recommending alcohol-free mouthwash to certain patients. The advertiser further noted that NAD has repeatedly held that “[t]he degree of sophistication of the target audience is a factor in determining the reasonable message conveyed by the advertising.”²⁰ The advertiser maintained that this advertisement provides dental professionals with an accurate ingredient comparison that they can consider, as they see fit, when deciding what mouthwash to recommend to their patients.²¹

Specifically, with respect to this claim, as it appears in the advertisement “Do you really know who you’re giving alcohol to?”, the advertiser stated that alcohol-based mouthwashes such as Listerine cause a certain amount of alcohol to be absorbed into the bloodstream and cause harm in some populations merely because of its contact with the tissues of the mouth. The advertiser argued that the advertisements in question do not equate using a mouthwash containing alcohol with consuming an alcoholic beverage but, rather, raises awareness amongst dental professionals of the high alcohol content of popular mouthwashes such as Listerine and cautions that this concentration of alcohol can be risky for some populations, even when the product is used as directed.

²⁰ Apple, Inc. (Power Mac G5), Report # 4155, *NAD Case Reports* (March 15, 2004) citing The National Concrete Masonry Association (Concrete Masonry Wall Systems), Report #4084, *NAD Case Reports* (August 2003); The Quaker Oats Company (Gatorade), Report # 3939, *NAD Case Reports* (August 2002).

²¹ To the extent that the challenger cited three FDA labeling and packaging requirements that it claims have not been met with respect to the BreathRx oral rinse product, the advertiser asserted that it has strived to follow all applicable federal regulations and will ensure that all future productions of BreathRx oral rinse comply with applicable FDA regulations but that, in any event, the challenger should direct its objections to FDA because technicalities about the construction of the tamper resistant seal do not raise any false advertising issues.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 10

It was the advertiser's position that trained medical professionals, to whom this advertisement is directed, understand that alcohol-based mouthwash is not a beverage intended to be consumed but may be unaware of the high amount of alcohol in mouthwashes such as Listerine. Further, to the extent that the challenger explains that the alcohol is included in its product only to solubilize the active ingredients, or that it is "denatured" to make it unpleasant to taste (thereby somehow altering the chemical composition or toxicity of the alcohol), the advertiser countered that this is immaterial²² – the truth is that Listerine does contain 21.6% alcohol²³. Similarly, the advertiser argued, the challengers assertions that the alcohol in Listerine "is regulated by the Bureau of Alcohol, Tobacco and Firearms" and that "Listerine has never been promoted for ingestion" are of no consequence. The advertiser asserted that it neither states nor implies that Listerine is intended for consumption but, rather, communicates important information about the high alcohol content of certain mouthwashes because "as soon as alcohol comes into contact with the tissues of the mouth and throat, absorption begins."²⁴ Moreover, the advertiser argued, some consumers may inadvertently or deliberately ingest mouthwash, notwithstanding its indicated use such that some of the alcohol in mouthwashes such as Listerine enters the bloodstream of the user, rendering the advertiser's reference to "giving alcohol" wholly accurate.

The advertiser noted that Listerine contains ethanol, the same alcohol that is commonly used in alcoholic beverages; for example, vodka is 40% ethanol. Further, although the denatured alcohol in Listerine is not drinkable, all of the additives that have "denatured" the alcohol are themselves safe for consumption in varying amounts. While the addition of the active ingredients may render Listerine undesirable as a beverage, the fact that the alcohol in Listerine is denatured does not and should not prevent the advertiser from accurately depicting Listerine's alcohol content.

The advertiser further asserted that the use of the phrase "43 proof" in the advertisement is accurate and truthful because it simply states the quantity of alcohol in the newer formulations of Listerine. The advertiser explained that "proof" is a common measurement of the concentration of alcohol in a water-alcohol mixture and is generally determined by doubling the percentage of alcohol in the liquid. Moreover, the advertiser contended, proof is the most commonly understood measurement of the percentage of alcohol in liquid. Even professional journals refer to the proof of alcohol-based mouthwashes, such as in an article about the role of dentists in screening for alcoholism that appeared in The Journal for Applied Research. The article states that "[a]lcohol in mouthwash can be as high as 54-proof liquor (beer is 5% to 7% alcohol, and

²² The alcohol in Listerine is a specially denatured alcohol, which means that certain additives in quantities generally up to 10% are added to otherwise potable ethanol to make it unpleasant to drink, but these additives do not remove from the alcohol its intoxicating qualities or alter the chemical integrity of the ethanol molecule. See, www.pharmco-prod.com/pages/alcholintro.html.

²³ The advertiser noted that original formula Listerine Antiseptic Mouthwash contains 26.9% alcohol, while the newer flavors, including Natural Citrus, Cool Mint, and FreshBurst contain 21.6% alcohol.

²⁴ See Alcohol and the Physiology of the Human Body, www.acs-corp.com/news.php?id=7

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 11

wine is 12% alcohol). . . . Listerine, as a mouthwash, is known to contain 26.9% alcohol, which is more than 5 times the alcohol concentration of beer and more than twice that of table wine.”²⁵

The advertiser added that besides being truthful, its claims about the alcohol content of some mouthwashes relative to BreathRx provides a material ingredient comparison and NAD has recognized that not only is it important for advertisers to be able to distinguish their products from competing products based on differences in ingredients, but allowing advertisers to make straightforward ingredient comparisons is actually beneficial to the targeted audience.²⁶ The advertiser asserted that its ingredient comparison is particularly helpful given the negative effects that have been associated with alcohol-based mouthwashes in certain populations:

i. Children

The advertiser noted that there are several valid reasons why dentists may want to recommend alcohol-free mouthwash to adult members of households containing children and, in fact, the Listerine label itself states that Listerine should not be used by children under age 12. The ADA Council on Dental Therapeutics requires manufacturers of mouthwashes that contain more than 5% alcohol and that carry the ADA seal of acceptance to place child safety caps and warning labels on the bottles because of reported cases of mouthwash-induced hypoglycemia and fatal poisoning.²⁷ In addition, the Children’s Hospital of Philadelphia recommends that parents use a non-alcoholic mouthwash because “[m]outhwash attracts children because of its bright color and sweet minty taste. When swallowed by your child, alcohol can produce serious toxic effects, requiring medical treatment for the child.” The advertiser noted that several cases have been reported of poisoning in children followed by consumption of alcohol-based mouthwash and the American Academy of Pediatrics has long observed that such mouthwashes are extremely hazardous because they are thought to be innocuous.

The advertiser rejected the challenger’s argument that its claim implies that BreathRx is 100% safe for children of all ages – especially in this context, where the advertisement is disseminated only to dental professionals who are educated as to the types of ingredients in oral care products.

ii. Recovering Alcoholics

According to the advertiser, there is a consensus that recovering alcoholics should avoid alcohol-based mouthwashes because of the vulnerability they have to relapse, which can be aggravated by the smell or taste of alcohol alone. The Academy of General Dentistry encourages dentists to familiarize themselves with the diseases of alcoholism and chemical dependency so they

²⁵ E. E. Ehikhamenor, Screening For Alcoholism: What Role For The Dentist?, The Journal of Applied Research, Vol. 4, No. 1 (2004), at 145

²⁶ citing PacificHealth Laboratories, Inc. (Endurox R4 Sports Drink), Report # 3671, *NAD Case Reports* (July 1, 2000).

²⁷ citing Sushma Nachnani, B.S., M.S., The Effects of Oral Rinses on Halitosis, UCLA School of Dentistry, p. 6, 7

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 12

understand the potential impact of mouthwash on their patients' sobriety.²⁸ The effect is significant, because “[e]ven after an addict has been sober for years, introduction of any chemical that affects the brain's pleasure centers has the potential to trigger a return to active addiction that is as strong as it was the day the addict stopped using....[moreover a] recovering drug addict or alcoholic can be triggered by . . . even the alcohol in mouthwash.”²⁹ This risk, the advertiser noted, is why many people in recovery are advised to use alcohol-free mouthwash, and why the advertiser lists this patient group for whom an alcohol-free alternative may be preferred.

iii. Xerostomia Patients and Conditions that Cause Xerostomia

The advertiser explained that Xerostomia (or “dry mouth”) is a common cause of oral malodor and it is widely accepted that commercial mouth rinses that contain alcohol may destroy the oral mucosa and that patients with Xerostomia should avoid them such that the listing of patients with Xerostomia is entirely truthful. The advertiser further noted that several other conditions can lead to Xerostomia, which can cause oral malodor, and dentists may want to recommend that patients who have those conditions use alcohol-free mouthwash. For example, patients with diabetes mellitus, particularly those with poor glycemic control, are more likely to complain of Xerostomia, certain medications also cause Xerostomia and smokers and the elderly are particularly vulnerable to Xerostomia. In addition, radiation therapy on the head and neck can injure the major and minor salivary glands, causing varying degrees of temporary or permanent Xerostomia. The advertiser asserted that it is up to the dental professional to decide whether any particular patient in these categories should avoid alcohol-based mouthwash but it is entitled to draw attention to the issue of patients at risk for Xerostomia so that a medically appropriate recommendation can be made.

iv. Pregnant and Lactating Women

The advertiser stated that it is widely accepted that pregnant women should avoid alcohol. In February 2005 the United States Surgeon General issued a press release stating: “We do not know what, if any, amount of alcohol is safe [for pregnant woman]. But we do know that the risk of a baby being born with any of the fetal alcohol spectrum disorders increases with the amount of alcohol a pregnant woman drinks, as does the likely severity of the condition. And when a pregnant woman drinks alcohol, so does her baby. Therefore, it’s in the child’s best interest for a pregnant woman to simply not drink alcohol.” The advertiser stated that pregnant women and lactating mothers are encouraged to refrain from ingesting any alcohol which may be passed on to their child and users of alcohol-based mouthwashes absorb alcohol even when used properly. Thus, the advertiser stated, it is reminding dentists that they may not want to dispense a mouthwash containing alcohol to these patients.

v. Patients With Restorations

²⁸ Steven Diogo, When your patient is an addict: Understanding addiction and recovery issues can help you better manage your patients and protect your practice, AGD Impact, Vol. 33, No. 9 (Dec. 2003)

²⁹ Id.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 13

The advertiser stated that dentists recognize that patients with dental restorations should avoid alcohol-based mouthwashes because alcohol is a solvent that can dissolve the bonding and composite materials used in dental restorations.³⁰ As such, its advertisement makes dentists aware that there are viable alcohol-free mouthwashes available for patients with dental restorations.

DECISION:³¹

I. Disclosure of Material Connection of Expert Endorser to Discus Dental, Inc.”

§ 255.5 of The FTC Guides Concerning Use of Endorsements and Testimonials in Advertising makes clear that, regarding disclosure of material connections of an endorser to an advertiser:

When there exists a connection between the endorser and the seller of the advertised product which might materially affect the weight or credibility of the endorsement (i.e., the connection is not reasonably expected by the audience) such connection must be fully disclosed. An example of a connection that is ordinarily expected by viewers and need not be disclosed is the payment or promise of payment to an endorser who is an expert or well known personality, as long as the advertiser does not represent that the endorsement was given without compensation. However, when the endorser is neither represented in the advertisement as an expert nor is known to a significant portion of the viewing public, then the advertiser should clearly and conspicuously disclose either the payment or promise of compensation prior to and in exchange for the endorsement or the fact that the endorser knew or had reasons to know or believe that if the endorsement favors the advertised product some benefit, such as an appearance on TV would be extended to the endorser.

Although the advertiser offers that Dr. Dorfman is a “celebrity” he is also, unquestionably the co-founder and owner of Discus Dental with more than a substantial financial interest in the success of BreathRx products. Assuming *arguendo* that Dr. Dorfman can be considered a “celebrity” in the truest sense and of the type contemplated by the FTC Guidelines, the challenger asserted, and NAD agreed, that the advertiser cannot overcome the “material connections” disclosure by reliance on the exemption for expert and celebrity endorsers. There is nothing in the FTC Guidelines from which one could presume that the exemption assumes that it would be known to the viewing public that the celebrity endorser has other material

³⁰ See J. Penugonda, Alcohol-containing mouthwashes: effect on composite hardness, 1: J. Clinical Dent. Vol. 5, No. 2 (1994)

³¹ To the extent that the challenger took issue with the truth and accuracy of the claims “America’s #1 Dentist Dispensed Breath Care System” and “Clinically proven more effective at fighting bad breath than leading brands, including Listerine”, based on evidence presented by the advertiser that these claims were the subject of federal litigation at the time of the instant proceeding, pursuant to NAD/NARB Procedures § 2.2 (B)(i), NAD administratively closed the matter as pertains to the truth and accuracy of these claims, with leave to re-open should the litigation not resolve the matter. In any event, notwithstanding the foregoing, NAD reviewed the advertiser’s use of the claim “America’s #1 Dentist Dispensed Breath Care System.”

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 14

connections to the company apart from his or her fee, such as being a financial stakeholder in the company.

The advertiser points to an example of the celebrity exemption provided in the FTC Guidelines, where a film star endorses a particular food product and the endorsement only points to taste and individual preference, and even though substantial, neither the fact nor the amount of the compensation need be revealed. However, in the instant matter, the “celebrity” at issue is not merely speaking of taste or “preference” but recommending, in his professional capacity, a product that is within his area of expertise and while the *amount* of his fee might be inconsequential, NAD determined that the *type* of compensation received and his vested interest in the promotion of the product and its continued success is not one that a viewing consumer would ordinarily expect.³² Dr. Dorfman is founder and owner of the company that makes the product for which he is making the endorsement in his professional/“celebrity” capacity – a fact that NAD determined should be disclosed to the viewing audience.

NAD observed that in the commercials at issue, when Dr. Dorfman introduces himself as, “Dr. Bill, the dentist from Extreme Makeover” a super appears next to him reading, “Co-Founder” over the logo for Discus Dental. NAD questioned the adequacy of the disclosure with respect to the information it conveyed. While the disclosing that Dr. Dorfman is co-founder of Discus Dental, NAD determined that the disclosure should more accurately read “owner and co-founder” so as to better qualify that the spokesperson *still* maintains a financial interest in the promotion of BreathRx.

Further, NAD determined that, given the materiality of the connection between the endorser and the product, the reference to “Discus Dental” beneath the “co-owner” disclosure, did not adequately apprise the viewer of the endorser’s specific connection to the product being touted – in other words, that this company (Discus Dental) is the maker of “BreathRx Fresh Breath System” (the logo for which appears at several intervals in the commercials at issue). NAD concluded that it was Dr. Dorfman’s connection to the *BreathRx Fresh Breath System* that was the material information that needed to be conveyed to the viewer. Therefore, NAD recommended that the advertising at issue be modified so as to better disclose Dr. Dorfman’s material connection to the product *BreathRx Fresh Breath System*, not merely to Discus Dental. (e.g. co-owner and founder of Discus Dental, maker of the BreathRx System). Of course, how the advertiser chooses to achieve this end is entirely up to the advertiser.

II. Use of “Rx” Symbol on Products and in Advertising:³³

³² Unlike, for example, Martha Stewart touting the Martha Stewart Collection for K-Mart.

³³ With respect to the challenger’s assertion that the claim “Professional Formula” added to the implication that the products are prescription or prescription strength products, NAD acknowledged and accepted the advertiser’s assurances that it was already in the process of changing this aspect of its label (to discontinue this claim) prior to the commencement of the instant challenge.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 15

Preliminarily, to the extent that the advertiser asserted that its BreathRx label does not contain the Rx symbol and that the letters Rx do not stand alone and are fully incorporated into the product name BreathRx such that it is not apt to cause any confusion, NAD did not agree. NAD observed that whether “incorporated” into the name or not, the “Rx” appears as the typical symbol, that being a capital “R” with the “x” aligned next to, and across, the bottom right diagonal of the “R.”

As the advertiser points out, in the case of Merial Limited (FRONTLINE Plus Flea and Tick Treatment), NAD determined that consumers are accustomed to medical professionals (i.e., veterinarians) recommending and dispensing non-prescription products.³⁴ However, unlike the instant matter, in that case, NAD was concerned with the implications of using a veterinarian in a white lab coat in a veterinarian’s office for a product named “Frontline” – a product that was *solely* available at veterinarians’ offices without a prescription – NAD was *not* dealing with a product that was once only available thru dental offices but now available via dental offices and general consumer outlets such as CVS or Walgreens. More importantly, in Merial, NAD was not confronted, as it is here, with a product whose name contained the impactful “Rx” letters which have been recognized by both the FTC and FDA as having the potential to imply that a product (cosmetic or otherwise) is, in fact, a medicinal preparation or prescription strength.

Both the Food and Drug Administration (“FDA”) and NAD have recognized that the use of the “Rx” symbol to market non-prescription products may be inappropriate in certain instances. Although the advertiser contends that a commonly understood definition of the letters “Rx” is “a remedy, cure, or solution for a disorder or problem”³⁵ NAD observed that another commonly understood definition for “Rx” is “symbol used at the beginning of a prescription ; a medical prescription.”³⁶

In the case of Hornell Brewing Company (Arizona Rx Memory Mind Elixir), NAD determined that, “the term ‘Rx Memory’ may be misleading to consumers because the letters ‘Rx’ are recognized as a professional symbol used by physicians to instruct pharmacists in the formulation of specific prescriptions, a concern that has been recognized by the [FDA].”³⁷ In

³⁴ See, e.g., Merial Limited (FRONTLINE Plus Flea and Tick Treatment), Report # 3844, *NAD Case Reports* (12/18/2001) (NAD held that the presence of a veterinarian in a white coat in a television commercial recommending the flea and tick treatment product did not create the false impression that the product was a prescription product.

³⁵ Citing the American Heritage Dictionary of the English Language, Fourth Edition (2000).

³⁶ See, Merriam-Webster Dictionary at <http://www.m-w.com/dictionary/Rx>

³⁷ Hornell Brewing Company (Arizona Rx Memory Mind Elixir), Report # 3736, *NAD Case Reports* (March 8, 2001). NAD noted that, in one FTC action, a company stipulated (#2921) to cease and desist from:

“The use of the letters ‘Rx’ or other letters, signs or symbols which cause or have or may have the capacity to cause the impression or belief that its cosmetic or toilet goods are in fact medicinal preparations or that each parcel is individually compounded in accordance with a specific prescription therefore.” *Do’s and Don’ts of Advertising, Council of Better Business Bureaus* 19-111,112 (1997).

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 16

fact, NAD noted in that case that the FDA observed that in the case of dietary supplements, the use of the term “Rx” may deceive consumers into thinking that they are purchasing drugs without a prescription.³⁸ However, of note, in Hornell Brewing Company (Arizona Rx Memory Mind Elixir), NAD did *not* make a determination that Rx necessarily implies a prescription or prescription strength attribute. In fact, NAD specifically stated that “[t]he issue for NAD was not whether consumers will confuse the product with a prescription drug but whether the label claim “Rx Memory Herbal Tonic” implies that consumption of this product will benefit memory.”

As the challenger noted, the FDA recently issued a Warning Letter to the makers of “Arizona Rx Stress Relief Elixir” stating, among other things, that the use of “Rx” caused the product to be misbranded, noting that this symbol appears in several locations on the label which also bore statements including, but not limited to, “A Safe and Certain Remedy.” The FDA stated that, in the context of the labeling as a whole this suggested that the product is a prescription product and warned that, “the label must be revised so that the prescription symbols and the other phrases and terms that suggest this product is a Rx drug are removed from this label.”³⁹

In the instant case, the federal litigation precludes a determination by NAD as to the actual performance capability of the advertiser’s product. However, assuming *arguendo*, that the advertiser’s clinically proven performance claims and “#1 Dentist Dispensed System” claims are true, NAD must determine whether the advertiser’s use of “Rx” in its product name, conveys the message that consumers can now purchase prescription oral care products without a prescription.⁴⁰

NAD has held that generally “[a]bsent extrinsic evidence that consumers have been confused or misled, NAD will not require an advertiser to change the name of a product simply because the challenger speculates that it might be misleading,”⁴¹ however, such recommendations of a product name change are not without precedent.⁴² NAD acknowledged the challenger’s concerns regarding the proximity of the product name to the claim “America’s #1 Dentist Dispensed Breath System” on product packaging, however, keeping in mind that dentists do, in fact, often

³⁸ Id.

³⁹ See FDA Warning Letter ONPLDS 02-00, May 15, 2000.

⁴⁰ Contrary to the advertiser’s assertion, the mere fact that a product bearing the term “Rx” is sold over the counter alongside other non-prescription oral hygiene products does not, by itself, demonstrate that the use of the phrase “Rx” in the product name is not confusing or misleading.

⁴¹ Coca-Cola Company (Powerade Option Low Calorie Sports Drink), Report # 4438, *NAD Case Reports* (January 12, 2006); Bissell Homecare, Inc. (Bissell QuickSteamer® Plus, Bissell PowerSteamer® Plus ProHeat® Deep Cleaning Machines), Report # 4145, *NAD Case Reports* (February 13, 2004); CCA Industries, Inc. (Scar Zone Topical Scar Diminishing Cream with SPF15 and Silicone), Report # 4018, *NAD Case Reports* (March 2003); IGIA (Never Snore), Report # 3968, *NAD Case Reports* (November 2002).

⁴² Hornell Brewing Company (Arizona Rx Memory Mind Elixir), Report #3736, *NAD Case Reports* (March 2001); see also, Warner Lambert Company v Breathasure, Inc., 204 F.3d 87(2000).

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 17

dispense and/or recommend various products, on this record, NAD could not conclude that the advertiser's use of Rx in its product name as it appears on current product packaging is *per se* misleading absent consumer perception evidence demonstrating that such is the case.

However, with respect to the context in which the BreathRx product name appears in the television commercials (emblazoned across the screen), NAD arrived at a different conclusion. The commercials contain various individuals who use different products to "mask" their bad breath problem including one man (who describes himself as a "rinser") pictured alongside a multitude of mouth rinse bottles— thereby implying that BreathRx is different from these other products. The lead spokesperson, "America's Dentist" Dr. Dorfman, touts that he recommends this product to his "patients," that "only BreathRx has Zytex which eliminates bacteria, neutralizes odor...and it's clinically proven to stop bad breath before it starts." These claims are accompanied by an extreme animated visual close-up of what appear to be Zytex molecules and strains of bacteria in the mouth. Thereafter, the voiceover proclaims that BreathRx "was only available in dentists' offices" thereby adding to the perception that the BreathRx system offers prescription strength attributes, and in fact, the voiceover concludes by urging the consumer to "ask your dental hygienist" and to "give science a try" and get BreathRx.

In the context in which it appears in the television advertisements in the instant challenge, and in light of the representations made therein, NAD determined that a consumer could reasonably conclude that the advertiser's product name, BreathRx, reasonably implies that consumers can now purchase prescription oral care products without a prescription or the intervention of a dental professional. As such, NAD recommended that the advertiser modify its television commercials to avoid the implication that by purchasing BreathRx, consumers are getting prescription strength oral care products.⁴³

III. Use of the Claim "America's #1 Dentist Dispensed Breath Care System" on Individual BreathRx Products:

Preliminarily, NAD appreciated the advertiser's voluntary discontinuance of its use of "America's #1 Dentist Dispensed Breath Care System" claim from its Anti-Bacterial Breath Spray packaging, a measure that NAD believed to be warranted as this product is not now, nor has it ever been promoted here by the advertiser as, a component of the BreathRx System.

⁴³To the extent that the advertiser points to other instances where the letters "Rx" have been used in a variety of non-prescription products (i.e., Frederic Fekkai Protein Rx Reparative Treatment Mask; Met-Rx Big 100 Meal Replacement Bar and Met-Rx Meal Replacement Powder; and Arth-Rx topical analgesic), this is immaterial to the instant inquiry. NAD's review concerns this advertiser in this proceeding, who is responsible for providing substantiation for all reasonable interpretations of its own claims. Further, to the extent that the advertiser points to the fact that, after modifying the claims on its product labels following a determination by NAD (Hornell Brewing Company (Arizona Rx Memory Mind Elixir), Report # 3736, *NAD Case Reports* [March 8, 2001]), Arizona Beverage Company continues to use the Rx symbol in its Rx Memory, Rx Stress, and other herbal beverages, NAD simply notes that the advertiser in that case is doing so *in violation of NAD's decision* and, again, this advertiser has received a warning letter with respect to its Rx Stress Relief beverage, from the FDA demanding that the label be revised (emphasis added) "so that the prescription symbols and the other phrases and terms that suggest this product is a Rx drug *are removed*."

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 18

To the extent that the advertiser asserts that the challenger's position that each product does not enjoy #1 status (as it relates to the truthfulness of the #1 Dispensed System Claim), is not subject to NAD review because the claim itself is the subject of litigation, the advertiser is wholly incorrect. While the *truthfulness* of the #1 Dentist-Dispensed System claim is not the subject of the instant inquiry, the advertiser's *use* of this claim on individual products and the implied claim that each product enjoys this status is subject to NAD's review. However, As the advertiser noted, NAD will assume "for the purpose of this challenge, that the #1 Dispensed System *Claim* is substantiated."

With respect to the advertiser's use of this claim on the individual components of the BreathRx Fresh Breath System as well as on the dental floss, it is well established that an advertiser is obligated to support all reasonable interpretations of claims made in advertising including messages it may not have intended to convey.⁴⁴ In the absence of any communication data concerning messages that consumers could reasonably take away from the challenged product packaging claims, NAD uses its own expertise to evaluate whether any implied messages were conveyed.⁴⁵

NAD determined that the product packaging and advertisements overall reasonably conveyed the message that the BreathRx Fresh Breath System consisted of three steps: (1) Brush; (2) Scrape (including spraying and scraping); and (4) Rinse, with no indication that the Dental Floss was a genuine component of this "System."

NAD observed that, in its first submission, the advertiser repeatedly referred to the BreathRx System as a three-step treatment "consisting of (1) brushing with the BreathRx toothpaste; (2) scraping the tongue with BreathRx tongue spray and scraper; and (3) rinsing with BreathRx mouth rinse." The advertiser itself then detailed each of the elements of these three steps. Indeed, throughout its first submission, at no time when speaking of the BreathRx System, did the advertiser mention its dental floss as a component.

NAD further noted that *none* of the commercials at issue in this challenge depict the dental floss product at all, let alone state that its use is a component of the BreathRx Fresh Breath System. In fact, one commercial specifically outlines that "It's just three easy steps...Brush, Scrape, Rinse" (with accompanying text: 1 Brush; 2 Scrape 3-Rinse simultaneously appearing onscreen.)

In its second submission, the advertiser reiterated that (emphasis added):

"[t]he BreathRx Breath System consists of *three main steps*, 'Brush,' 'Scrape,' 'Rinse.' The product labels bear a logo that shows the *three main steps* in the system together,

⁴⁴ See, The Valvoline Company (Zerex G-05 Extended Life Antifreeze), Report #4375 (August 2005); McNeil, PPC, Inc. (Tylenol Arthritis Pain), Report #4247, NAD Case Reports (November 2004); Bayer Corporation (Aleve), Report #4126, NAD Case Reports (December 2003).

⁴⁵ See, The Valvoline Company (Zerex G-05 Extended Life Antifreeze) *supra*; Bayer Corporation (Aleve), *supra*.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 19

with that product's applicable step highlighted in white. In addition, *each main step has its own icon* utilizing a descriptive graphic and text..."

NAD further noted that the back panel of each component's packaging contains three icons representing the three steps (with that component being "highlighted", i.e., each reads "Step 1" with accompanying "toothbrush" icon alongside the word "Brush" (with no mention of floss); "Step 2" with accompanying "scraper" icon alongside the word "Scrape"; and (3) "Step 3" with accompanying "wavy lines" icon alongside the word "Rinse."

In its second submission, for the first time, the advertiser asserts that *two* of the main steps in the system have more than one component, i.e., that not only does Step #2 the "Scrape" step consist of two steps of spraying the tongue, then scraping, but that Step #1 now includes brushing *and flossing* as demonstrated by the "Brush and Floss" icon that appears on the new dental floss packaging and in more recent advertisements.

In the first instance, NAD observed that as of the time of the writing of this decision, the introduction on the advertiser's website⁴⁶ clearly sets forth the three steps as outline above. On this page of the site, Step 1 states simply, "Brush" – not brush and floss – with a visual icon of the toothbrush and a large visual of the toothpaste tube (along with copy describing the toothpaste's attributes). It is only if one clicks on the word "Brush" that one arrives at a page where the dental floss product sits atop a column, above the toothpaste products, but the copy still makes no mention of the floss as a component of any "Brush & Floss" step. Rather, the text next to the depicted dental floss simply states, "Enhance your oral care regimen with BreathRx Floss with Zytex" without any mention of any "Step."⁴⁷

Moreover, the website touts the New "BreathRx Starter Kit" as follow (emphasis added):

"Start taking control of your breath today! The BreathRx Starter Kit ... has the essential products you need to integrate *the simple 3-Step, Brush-Scrape-Rinse* routine into your daily hygiene regimen.... With the BreathRx Starter Kit, you've got nothing to lose but your bad breath! Contains (1) Purifying Toothpaste- 4oz tube, (2) Gentle Tongue Scrapers, (1) Anti-Bacterial Tongue Spray- 2oz bottle, and (1) Anti-Bacterial Mouth Rinse- 8fl oz.

Even the "BreathRx Essentials" kit featured on the website states, in relevant part, "Each kit has the products you need to integrate *the simple 3-Step, Brush-Scrape-Rinse* routine into your daily hygiene" and fails to include the dental floss at all, let alone as part of any "Step."

NAD accepted that Step #2 ("Scrape"), in fact, consists of two elements – spraying the tongue with Anti-Bacterial Tongue Spray to loosen and kill odor-causing bacteria, and then scraping. While the icon for this step consists only of a visual of the scraper on reads, "Scrape" (and not,

⁴⁶ <http://www.breathrx.com/home.php>

⁴⁷ The icon on the dental floss packaging is too small to be legible.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 20

for example, “Spray & Scrape”), NAD observed that the Antibacterial Tongue Spray is packaged together with the Scraper as a “unit” and the product instructions on this unit further direct the consumer to use these two items *in tandem*, i.e., to use the spray to loosen and kill odor causing bacteria and then scrape the bacteria away.⁴⁸

In contrast, NAD determined that the dental floss (recent advertisements and product packaging for the floss notwithstanding) are not, in fact, part of the advertiser’s three-step system but, rather, is a separate and distinct act from brushing.

In the first place, NAD observed that, unlike the Antibacterial Tongue Spray and Scraper which are packaged together, the dental floss and toothpaste are packaged separately. Further, the toothpaste product packaging contains the Step 1 icon (graphic of the toothbrush) and the text reading, “Brush” when, according to the advertiser, this step consists of “Brush & Floss.”⁴⁹ Thus, if NAD is to credit the advertiser’s argument that the dental floss is in fact, part of Step 1 (and a component of the entire System), NAD concluded that a consumer purchasing solely the toothpaste could reasonably be misled into believing that he or she is purchasing “Step 1” in its entirety and that Step 1 consists of one component, when, according to the advertiser, in fact that is not the case; the consumer will only be receiving one half of this step.

NAD further observed that while the front panel of the dental floss packaging may have a *new* icon (depicting the same toothbrush symbol but with revised text reading, “Brush and Floss), *none* of the other products in the BreathRx Fresh Breath System carry this new Step 1 icon that appears on the front of the dental floss. All other products (i.e., the Introductory Kit,⁵⁰ Scraper “unit” or even the toothpaste which is purportedly only one half of step one) have the “toothbrush” icon and the word “Brush” as Step 1. Further, the *back panel* of the dental floss packaging (like the other products) contains the same three icons as the other products with the words “Brush” (with the toothbrush symbol), “Scrape” (with scraper symbol), and “Rinse” (with wavy lines symbol) and the instructions on the back panel of the dental floss make *no mention* of the purportedly concomitant part of this “step” of brushing. In fact, NAD noted, the product packaging of the toothpaste in the newer advertisements (claiming that “Step 1” is purportedly now comprised of the two components brushing and flossing), still bear the icon of the toothbrush symbol and the word “Brush.”

⁴⁸ To the extent that the advertiser’s website does sell the “scraper” separately (in packages of three) NAD noted that this packaging bears the Step 2 icon of the scraper such that, at the very least, the consumer is getting what is depicted on the product package (the spray does not appear to be sold separately).

⁴⁹ With respect to the Introductory Kit, the fact that the back panel’s instructions state “Brush and Floss” does not mitigate the confusion caused by the front panel and top of the back panel clearly use the Step 1 icon (“Brush” and graphic of toothbrush).

⁵⁰ Although acknowledging that text in the product directions appears on the back panel of the Introductory Kit regarding “Brush & Floss,” NAD observed that the front panel still contains the original icon of the toothbrush and the word “Brush” as does the top of the back panel outlining the three steps and explicitly stating that Step 1 is “Brush.”

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 21

In sum, NAD determined that the product packaging and advertisements conveyed the message that the BreathRx Fresh Breath System consisted of three steps: (1) Brush; (2) Scrape (including spraying and scraping); and (4) Rinse and that, therefore, the claim, “America’s #1 Dentist Dispensed Breath Care System” is improperly placed on product packaging for the dental floss (as is the phrase “brush and floss” in describing “Step 1 on the Introductory kit”). In fact, NAD questioned whether this seemingly new addition to the “System” was even part of the system at the time that the claim, “America’s #1 Dentist-Dispensed Breath Care System” was created.

However, with respect to the appearance of the claim “America’s #1 Dentist-Dispensed Breath Care System” on the purifying toothpaste, tongue spray/scraper and mouth rinse, NAD determined that it was not inappropriate that these three products, which actually comprise the “System,” bear this claim. The claim expressly reads (emphasis added) “America’s #1 Dentist-Dispensed Breath Care System” and, NAD concluded that while consumers may well purchase the System components separately, product packaging for each product delineates that particular component as a “Step” in the System. As such, for example, NAD did not agree with the challenger that as used on the BreathRx Mouth Rinse on a stand-alone basis this claim can only be interpreted as a superiority claim for BreathRx Mouth Rinse versus all other mouthwash products. Clearly the consumer is not purchasing a “System” but rather one step in the BreathRx System. Although the claim refers to a specific set of products sold and intended to be used together, this should not preclude the claim on individual components that consumers will purchase to replenish as part of the System.

For all of these reasons, NAD recommended that the advertiser remove the #1 Dispensed System claim from its dental floss packaging as well as any advertising claims offering this product as a component of Step 1.⁵¹ With respect to the Introductory Kit containing the three icons “Brush” (with the toothbrush); “Scrape” and “Rinse”, while including the dental floss in the package, NAD believed that the packaging bearing the claim “America’s #1 Dentist Dispensed System” would not be misleading as the “System” is clearly marked as containing these *three* steps of “Brush,” “Scrape,” and “Rinse”; the dental floss could easily be seen as a bonus product, however, NAD recommended that the back panel of the Introductory kit be modified so as to remove “floss” from that portion of the directions describing Step 1 as “Brush & Floss”.

IV. Characterization of the Alcohol Content in Listerine Claims:

The print advertisement at issue depicts a large BreathRx AntiBacterial Mouth Rinse bottle in the center of the advertisement. The headline reads, “Do you really know who you’re giving alcohol to?” and on the left side of the page is the instruction “Read the labels: Note the high percentage of alcohol shown in leading consumer breath rinses. BreathRx is 100% alcohol-free.” Below this language is a circled ingredient list of a mouthwash bottle showing 21.6% alcohol content with the text “A leading brand . . . THAT’S 43 PROOF!.” Immediately underneath that label is a portion of the BreathRx label with the words “Alcohol-Free” circled, accompanied by the text

⁵¹ Nothing in this decision precludes the advertiser from incorporating the dental floss into its “System” to make it a 4-Step system, however, it bears noting that this might clearly impact the truth and accuracy of the claim “America’s #1 Dentist-Dispensed Fresh Breath System.”

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 22

“BreathRx 100% alcohol-free.” On the right side of the advertisement is a list of individuals that the advertiser claims dentists should advise to avoid alcohol-based mouthwashes.⁵²

Preliminarily, although not specifically mentioned in this advertisement and while there is no picture of the challenger’s product, the comparison made is between BreathRx and the leading brands of which the challenger’s Listerine is clearly one. Indeed, other advertisements in this campaign make direct comparisons to Listerine. Further, it cannot be ignored that the alcohol content for the purportedly undesirable mouth rinse is 21.6%, which the advertiser acknowledges is the alcohol content of Listerine Natural Citrus, Cool Mint and varieties. Further, directly below the alcohol content listing for the undesirable mouth rinse appears another ingredient, “D&C Yellow #18” – a color often associated with Listerine.

It was the challenger’s position that these advertisements mischaracterized the alcohol content in Listerine (being a leading brand). In part, NAD agreed.

It is well established that, in an NAD proceeding, an advertiser is obligated to support all reasonable interpretations of its claims not just messages it intended to convey.⁵³ It is well-settled that although an advertisement may be literally accurate, it may nevertheless be misleading⁵⁴ or communicate an inaccurate message.⁵⁵ Here, neither party submitted communication data as to the reasonable takeaway from the challenged advertising. Consequently, in the absence of any reliable communication data, NAD used its own expertise to evaluate whether any implied messages were conveyed.⁵⁶

In its review of the subject advertisements, NAD gave serious consideration to the context and presentation of the challenged claims, and the fact that the intended target audience is undisputedly sophisticated professionals.⁵⁷ However, as noted in prior NAD cases, even a

⁵² In one version of this advertisement the list includes (in order, from top to bottom), Children (in Bold Print), Recovering Alcoholics, Elderly Patients, Pregnant and Lactating Women, Diabetics (in Bold Print), Patients on Medication.” In the second incarnation of this advertisement this list reads (again, in order from top to bottom): Children (in somewhat bold print; Recovering Alcoholics (in very bold print), Xerostomia Patients, Smokers, Patients with Restorations, Radiation Therapy Patients.” At the bottom of both advertisements appears the tagline: BreathRx . . . Your Advanced ALCOHOL FREE Alternative.”

⁵³ See, Swiss Research, Inc. (Shugr Sweetener), Report #4442, *NAD Case Reports* (January 2006); Patent HEALTH, LLC (Fluid Joint - Dietary Supplement for Joint Function), Report #4335, *NAD Case Reports* (May 2005); The Valvoline Company (Zerex G-05 Extended Life Antifreeze), Report #4375 (August 2005); Reckitt Benckiser, Inc. (Lysol Ready Brush Toilet Cleaning System), Report #4292, *NAD Case Reports* (March 2005).

⁵⁴ Menard, Inc. (Comparative Pricing), Report # 4017, *NAD Case Reports* (March 2003); The Coca-Cola Company (Powerade Sports Drink), Report #3930), *NAD Case Reports* (August 2002).

⁵⁵ Genmar Holdings, Inc. (Glastron SX 175 Runabout Boat), Report # 4107, *NAD Case Reports* (December 2003); Pfizer Healthcare (Revolution Topical Parasiticide), Report #3640, *NAD Case Reports* (May 2000).

⁵⁶ See, McNeil-PPC, Inc. (Tylenol Arthritis Pain), Report #4247, *NAD Case Reports* (November 2004); A.D. Pharma, Inc. (notox), Report #4163, *NAD Case Reports* (March 2004).

⁵⁷ The National Concrete Masonry Association (Concrete Masonry Wall Systems), Report #4084 (August 2003).

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 23

sophisticated audience is entitled to truthful and accurate messages with respect to the products they choose to purchase.⁵⁸ Likewise, health professionals are entitled to the same truthful and accurate messages with respect to products they may well recommend to their patients. NAD determined that, notwithstanding that this advertisement is disseminated in professional journals, the claims regarding alcohol-based mouth rinses, even if literally true, in certain instances presented the potential to convey unsupported messages.

In the first instance, it is undisputed that mouth rinses are not designed nor promoted for ingestion. On the one hand, the advertiser purports to be disseminating valuable information to sophisticated health professionals, yet the advertisements in question use colloquialisms and lay terms in such a manner as to present this information in quite another light. NAD determined that the advertiser's use of the term "PROOF" here connotes alcohol as one might purchase for consumption. Indeed, notwithstanding that the article cited by the advertiser in support of its position stated that the "alcohol in mouthwash can be as high as 54 proof liquor..." it did *not* refer to *mouth rinses* as being "54 PROOF" and, notably, the advertiser does not present this information in the same manner as the article. As such, notwithstanding that the advertisements in question are targeted to dental professionals, NAD recommended that the advertiser discontinue use of the word "PROOF" and avoid any use of this term that potentially equates rinsing with an alcohol-based mouth rinse to alcohol that is designed and promoted for ingestion. Similarly, NAD believed it to be inaccurate to equate recommending or even dispensing a mouth rise to "giving alcohol"— a message that connotes even inadvertent encouragement of alcohol consumption – and recommended that this phrase be discontinued.

i. Children

In the first instance, as the challenger pointed out, although containing a percentage of alcohol, Listerine has never been promoted for children and, in fact, the product packaging contains a warning cautioning, "Do not administer to children under 12 years of age" and that they should "[k]eep out of reach of children." NAD takes no issue with the advertiser's desire to remind dentists of the implications of recommending/dispensing an alcohol-based mouth rinse to a patient who has young children in the home, however, as presented here, the advertiser implied that its BreathRx mouth rinse is, without qualification, safer for use by children *in general* when, in fact, that is not necessarily the case. The BreathRx mouth rinse label clearly cautions, "Do not administer to children under age six" and to "[s]upervise use for children between ages six and twelve." Clearly neither of these mouth rinses should be administered to children under six years of age – period – irrespective of their alcohol content. As such, NAD recommended that the advertiser remove the inclusion of "children" from its message regarding the dispensing of alcohol-based mouth rinses, or otherwise modify this claim to limit this claim to use of alcohol-based mouth rinses by children between the ages for six and twelve but nonetheless reminding these professionals that even use of BreathRx by this age group be supervised.

⁵⁸ See, Apple Computer, Inc. (Power Mac G5), Report #4155, *NAD Case Reports* (March 2004); Oracle Corporation (9i Collaboration Suite), Report #4117, *NAD Case Reports* (November 2003).

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 24

ii. Recovering Alcoholics

To the extent that the advertiser asserted that there is “a consensus” that recovering alcoholics should avoid alcohol-based mouthwashes because of the vulnerability they have to relapse, which can be aggravated by the smell or taste of alcohol alone, NAD observed that the advertiser cited no source in support of this “consensus” or among whom this consensus exists. Notwithstanding this fact, the advertiser provided evidence in the form of one online article from Academy of General Dentistry encourages dentists to familiarize themselves with the diseases of alcoholism and chemical dependency so they understand the potential impact of mouthwash on their patients’ sobriety⁵⁹ and stated that “[e]ven after an addict has been sober for years, introduction of any chemical that affects the brain’s pleasure centers has the potential to trigger a return to active addiction that is as strong as it was the day the addict stopped using....[moreover a] recovering drug addict or alcoholic can be triggered by . . . even the alcohol in mouthwash.”⁶⁰ Thus, while NAD determined that employing language such as “Proof” to refer to other mouth rinses grossly exaggerated the nature of the alcohol contained in mouth rinses (indeed, since it is the presence of alcohol at *any* level – period – that might be of issue to the recovering alcoholic), and though acknowledging that mouth rinses are not designed nor promoted for ingestion, and keeping in mind that the advertisement in question is directed a health professionals and not the lay consumer, NAD believed it prudent to err on the side of caution. As such, NAD determined that a reasonable basis existed for the advertiser’s claim that dental professionals be made aware of the issue of alcohol-based mouth rinses insofar as it might pertain to their patients in recovery.

iii. Xerostomia Patients and Conditions that Cause Xerostomia

With respect to the advertiser’s listing of xerostomia (dry mouth, a common cause of oral malodor), and various conditions that may cause xerostomia, in the absence of any evidence to the contrary, NAD accepted as true that (notwithstanding that the challenger’s Listerine is not contra-indicated for xerostomia patients), mouth rinses containing alcohol *may* destroy oral mucosa and that patients with xerostomia should avoid them. However, NAD determined that this is not the same as telling dental professionals, unequivocally and without qualification, that they should not dispense mouth rinses that contain alcohol to “diabetics,” “smokers” “elderly patients” “radiation therapy patients” or “patients on medication.” The evidence in the record demonstrates, at best, that it is only certain diabetics who are “more likely” to complain of dry mouth. Similarly, not all smokers will suffer from xerostomia and, with respect to elderly patients, those patients on *certain specific* medications are more vulnerable to drug-induced xerostomia. In fact, one article cited by the advertiser states that “[d]octors and dentists no longer believe that old age by itself causes significant dry mouth.”⁶¹ Likewise, not all “radiation therapy patients” are more likely to complain of dry mouth but, rather, those undergoing radiation therapy on the head and neck.

⁵⁹ Steven Diogo, When your patient is an addict: Understanding addiction and recovery issues can help you better manage your patients and protect your practice, AGD Impact, Vol. 33, No. 9 (Dec. 2003)

⁶⁰ Id.

⁶¹ Harvard Health Letter, *Saliva Shortage: Seven tips for a dry mouth*, February 2005).

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 25

It is one thing for the advertiser to claim that dentists may want to avoid dispensing alcohol-based mouth rinses to patients with xerostomia or, generally, to patients at risk for xerostomia, but quite another to claim that dentists avoid dispensing alcohol-based mouth rinses altogether to the listed sub-groups. NAD determined that without specific qualification that it is due to these individuals increased chances of complaining of dry-mouth, there exists the implication that there is some *other* potential, perhaps even more grave, health risk involved in dispensing an alcohol-based mouth rinse to these individuals.

While NAD appreciates that it was the advertiser's intent to draw attention to the issue of the impact alcohol-based mouth rinses in patients suffering from Xerostomia (or those at risk) so that a more proper professional recommendation can be made, NAD determined that the advertisements at issue are overly broad and recommended that the advertiser significantly modify its advertisement so as to either limit its claim to "Xerostomia Patients," or generally to patients at risk for xerostomia, to clarify that these other sub-groups (and where applicable, within these subgroups, only *certain* individuals) *may* be more *likely* to complain of xerostomia and that this is the basis for perhaps avoiding alcohol-based mouth rinses.

iv. Pregnant or Lactating Women

With respect to the advertiser's listing of "pregnant or lactating women" as a group that dentists may wish to avoid dispensing alcohol-based mouth rinses, NAD observed that in support of this claim the advertiser pointed to a press release from the United States Surgeon General stating that it is unknown as to what, if any amount of alcohol is safe for pregnant women, that the risk of fetal alcohol syndrome increases with the amount of alcohol a woman *drinks* and that, when a pregnant woman *drinks* alcohol, so does her baby. To the extent that the advertiser offered an online article to the effect that a small amount of alcohol enters the bloodstream directly through tissues in the mouth, NAD noted this article makes *no* mention of pregnant women nor the use of mouth rinses containing alcohol by this population group and the record offers no correlation between the Surgeon General's statement and this article. As such, NAD determined that the evidence in the record was insufficient to provide a reasonable basis for the claim, even to sophisticated dental professionals, that dentists be cautioned against dispensing these competing mouth rinses to their patients who are or may become pregnant (or are lactating) or the implication that mouth rinses containing alcohol are, when used according to product use directions and not ingested, dangerous to pregnant or lactating women. As such, NAD recommended that the listing of "pregnant or lactating women" as a group that dentists may wish to avoid dispensing alcohol-based mouth rinses be discontinued.

v. Patients with Restorations

To the extent that the advertisement in question alerts dental professionals that they might want to consider not dispensing alcohol-based mouth rinses to patients with restorations, while again noting that use of other mouth rinses is not contraindicated by label directions, NAD could not ignore the abstract from the New York University College of Dentistry noting the effects of mouth rinses on composite resin hardness and the softening affect that was directly related to the

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 26

percentage of alcohol in the mouth rinse.⁶² Thus, NAD concluded that there existed a reasonable basis for the advertiser's claim that dental professionals be made aware of the issue of alcohol-based mouth rinses insofar as it *might* impact patients with restorative dental work.

Conclusion:

With respect to the endorsement of the BreathRx Fresh Breath System by Dr. Dorfman, NAD recommended that the advertising at issue be modified so as to better disclose Dr. Dorfman's material connection to the product *BreathRx Fresh Breath System*, not merely to Discus Dental.

Insofar as concerns the advertiser's use of "Rx" within its product name "BreathRx," NAD recommended that the advertiser modify its television commercials in accordance herein to avoid the implication that by purchasing BreathRx, consumers are getting prescription strength oral care products.

With respect to the advertiser use of the "America's #1 Dentist-Dispensed Fresh Breath System" on its system components, while not inappropriate on individual packaging of those actual products that actually comprise the System (i.e., the purifying toothpaste, tongue spray/scrapper and mouth rinse), NAD recommended that the advertiser remove this claim from its dental floss packaging as well as any advertising claims offering this product as a component of Step 1. With respect to the Introductory Kit, NAD recommended that the back panel of the Introductory kit be modified so as to remove "floss" from that portion of the directions describing Step 1 as "Brush & Floss."

As concerns the advertiser's claims characterizing the alcohol content in Listerine, NAD recommended that the advertiser discontinue use of the word "PROOF" to describe other mouth rinses, and otherwise modify its advertising so as not to equate recommending or dispensing a mouth rise to patients with "giving alcohol"—a message that NAD determined connotes even inadvertent encouragement of alcohol consumption. NAD determined that a reasonable basis existed for the advertiser's claim that dental professionals be made aware of the issue of alcohol-based mouth rinses insofar as it might pertain to their patients in recovery. NAD further determined that there existed a reasonable basis for the advertiser's claim that dental professionals be made aware of the issue of alcohol-based mouth rinses insofar as it *might* impact patients with restorative dental work. NAD also recommended that the advertiser significantly modify its advertisement so as to either limit its claim to "Xerostomia Patients" (or, more generally, patients at risk for xerostomia) or to clarify that these other sub-groups of elderly, diabetics, etc. (and where applicable, within these subgroups, only *certain* individuals) *may* be more *likely* to complain of xerostomia and that this is the basis for perhaps avoiding alcohol-based mouth rinses. NAD further recommended that the advertiser remove the inclusion of "children" from its message regarding the dispensing of alcohol-based mouth rinses, or

⁶² 80 hybrid composite discs were divided into eight equal groups: Listerine, Scope, Viadent, Plax, Lavoris, Clear Choice, and Rembrandt, with water acting as the control. All discs were immersed in their respective liquids for two minutes a day over a period of six months. The results indicated that the alcohol content in mouthwashes can affect composite hardness.

DISCUS DENTAL, INC.
BreathRx Oral Care Products
Page 27

otherwise modify this claim to limit this claim to use of alcohol-based mouth rinses by children between the ages for six and twelve but nonetheless reminding these professionals that even use of BreathRx by this age group be supervised. However, NAD recommended that the advertiser remove the inclusion of "pregnant or lactating women" from its message that dental professionals may want to refrain from dispensing alcohol-based mouth rinses to this patient population.

Advertiser's Statement:

Discus Dental thanks NAD for its careful consideration of the issues raised in this challenge. We are pleased that NAD upheld the name "BreathRx" and Discus Dental's right to display the descriptor "America's #1 Dentist-Dispensed Breath Care System" on the BreathRx products that are part of the BreathRx Fresh Breath System. We recognize that NAD has determined that BreathRx Dental Floss is not currently part of the BreathRx Fresh Breath System and we will begin to modify the necessary packaging in accordance with this decision. We also are gratified that NAD affirmed our right to compare the alcohol content of alcohol-free BreathRx Anti-Bacterial Mouth Rinse and Listerine Mouthwash and to promote the fact that alcohol-free BreathRx Mouth Rinse may be preferable for individuals with dental restorations, recovering alcoholics, and individuals with or at risk for Xerostomia. We appreciate that NAD recognized that BreathRx, unlike Listerine, may be used by children ages 6 to 12 when supervised. In addition, we understand that the decision does not foreclose us from informing dentists of the implications of recommending or dispensing an alcohol-based mouth rinse to an adult patient who has children in the home.

Although Discus Dental believes that the disclosure of Dr. Bill Dorfman's connection to the BreathRx Fresh Breath System is unnecessary pursuant to the FTC Guidelines and that, in any event, the disclosure that Dr. Dorfman is the Founder of Discus Dental is sufficient, we will take into account NAD's concerns in our future advertising. In addition, while we are gratified that NAD determined that the BreathRx name is not misleading to consumers, we disagree that the television advertisements convey that BreathRx is a prescription product. However, we will endeavor to address NAD's concern.

Finally, we do not agree with NAD's limited criticisms of the print advertisements comparing the alcohol content of BreathRx and Listerine, however, Discus Dental supports the self regulatory process and will take NAD's concerns into account with respect to future professional advertising. (#4473 MSZ, closed 04/14/2006)